



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

**STATEMENT
OF**

**TED ELKIN
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**FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**BEFORE THE
SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT, THE
FEDERAL WORKFORCE, AND THE DISTRICT OF COLUMBIA**

**COMMITTEE ON HOMELAND SECURITY AND
GOVERNMENTAL AFFAIRS**

UNITED STATES SENATE

**“AGRO-DEFENSE: RESPONDING TO THREATS AGAINST AMERICA’S
AGRICULTURE AND FOOD SYSTEM”**

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INTRODUCTION

Good afternoon, Chairman Akaka and Members of the Subcommittee. I am Ted Elkin, Director of the Office of Food Defense, Communication and Emergency Response for the Center for Food Safety and Applied Nutrition (CFSAN) at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to discuss our food defense activities.

Food safety and food defense continue to be top priorities for FDA. A terrorist attack on the food supply could have both severe public health and economic consequences, while damaging the public's confidence in the food we eat.

A great deal has been done over the past several years to enhance the safety and defense of the food supply in the United States. FDA has worked with other federal, state, local, tribal, and territorial food safety agencies, as well as with law enforcement and intelligence-gathering agencies, and with industry to significantly strengthen the nation's food safety and defense system across the entire distribution chain—from farm to table—to better protect our food supply against deliberate and accidental threats. This cooperation has resulted in greater awareness of potential vulnerabilities, the creation of more effective prevention programs, new surveillance systems, and the ability to respond more quickly to outbreaks of foodborne illness.

Further, the enactment of the FDA Food Safety Modernization Act (FSMA) in January of this year provides additional authorities and opportunities to protect our food supply from intentional and unintentional contamination.

In my testimony today, I will first briefly describe FDA's overall role in counterterrorism activities. Then, I will discuss our collaboration with our food safety and defense partners. I will also describe some of FDA's counterterrorism activities to enhance protection of the food supply. Finally, I will mention some of the food defense enhancements enacted in FSMA.

FDA'S Role in Food Related Counterterrorism Activities

FDA is the federal agency that regulates all of the food we eat except for meat, poultry, and processed egg products, which are regulated by our partners at the U.S. Department of Agriculture (USDA). FDA also is responsible for regulating tobacco products and ensuring that human drugs, human biological products, medical devices, and radiological products, as well as veterinary drugs, are safe and effective and that cosmetics are safe.

FDA's primary mission is to protect the public health. Ensuring that FDA-regulated products are safe and secure is a vital part of that mission. While performing our mission, we play a central and a leadership role in the nation's defense against acts of intentional contamination. It is FDA's goal, working closely with other government and private sector stakeholders, to reduce the likelihood that an FDA-regulated product could be used to poison or otherwise harm Americans. We also help ensure that the nation's public health system is prepared to deter a

potential threat and is ready to respond to an act of intentional contamination, including terrorism.

Collaboration With Food Safety and Food Defense Partners

In its food safety and defense efforts, FDA has many partners—federal, state, local, tribal, and territorial agencies; academia; and industry. FDA is working closely with our federal partners, such as USDA, the Department of Homeland Security (DHS), the Homeland Security Council at the White House, the Department of State, the Central Intelligence Agency (CIA), and the Federal Bureau of Investigation (FBI), to have the best information possible and to be prepared to act as needed.

FDA has been working closely with DHS and other federal agencies to implement the Homeland Security Presidential Directives (HSPDs). The Secretary of DHS is responsible for coordinating the overall national effort to enhance the protection of the critical infrastructure and key resources of the nation, including food and agriculture defense. HSPD-7, 8, and 9 identify critical infrastructures, improve response planning, and establish a national policy to defend the agriculture and food systems against terrorist attacks, major disasters, and other emergencies.

To implement HSPD-9, the HHS and USDA Secretaries or their designees exercise key responsibilities as food sector-specific agencies. DHS serves as the coordinator of the Food and Agriculture Sector within the Government Coordination Council (GCC). Within GCC, HHS and USDA serve as co-leads for the food sector. The GCC is charged with coordinating agriculture and food defense strategies, activities, and communication across government and between the

government and private-sector partners.

The Food and Agriculture Sector is a public-private partnership that combines expertise from several federal agencies (FDA, USDA, EPA, Department of Defense (DoD), Department of Commerce, Department of the Interior, and the Department of Justice), as well as that of state, local, tribal, and territorial officials (representing agriculture, public health, and veterinary services), and the private sector (more than 100 trade associations and individual firms participate). GCC members are currently developing a three-to-five year strategic plan, an education package for new members, and a strategic roadmap to help GCC meet the needs of private sector owners and operators and maintain the security and safety of the nation's food supply.

Now, I would like to describe some examples of FDA's other food defense activities.

Vulnerability and Threat Assessments

FDA's risk-based approach to food defense helps the Agency determine where to focus its resources. As part of its efforts to anticipate threats to the food supply, FDA has conducted extensive scientific vulnerability assessments of different categories of food, determining the most serious risks of intentional contamination with different biological or chemical agents during various stages of food production and distribution.

Over the past several years, FDA has continued to refine its approach and has undertaken more in-depth vulnerability assessments of specific food commodities, using a method called CARVER+Shock. This method uses processes adapted from techniques developed by DoD for use in assessing the vulnerabilities of military targets to asymmetric threats. Results of these updated assessments are being used to develop technology interventions and mitigation strategies, identify research needs, and provide guidance to the private sector.

FDA has used the CARVER+Shock method to perform vulnerability assessments to identify what an individual or group—intent on doing damage to the food and agriculture sector—could potentially do based on the person’s or group’s capability, intent, and past history. The CARVER+Shock methodology was modified under Homeland Security Council leadership for use in the food and agriculture sector by FDA, USDA, and DoD, with coordination by DHS, CIA, and FBI. FDA’s approach has been to seek voluntary, mutually beneficial partnerships with various segments of the food industry. We have completed such cooperative assessments with many segments of the regulated industry. FDA also has collaborated with USDA to provide assistance to the USDA Food and Nutrition Service on the use of this analytical tool on specific commodities in the school lunch program.

FDA has developed vulnerable assessment software based on the CARVER+Shock methodology and has made it available on FDA’s website to help processors, manufacturers, warehouse managers, and transporters in the food industry determine the vulnerability of individual food facilities to attack.

From 2005 to 2008, FDA was part of a joint federal initiative, along with USDA, DHS, and the FBI, called the Strategic Partnership Program on Agroterrorism (SPPA). The initiative brought these federal partners together, along with state and industry volunteers. The intent of the initiative was to collect the necessary data to identify food and agriculture sector-specific vulnerabilities to develop mitigation strategies, identify research gaps and needs, and increase awareness and coordination between government and industry partners. The results from these assessments have been used to identify mitigation strategies and to focus food defense research questions. Thirty-six vulnerability assessments were conducted under the SPPA initiative in direct support of HSPD-9. As required by HSPD-9, these assessments are re-evaluated every two years.

Preventive Training Tools for Government, Industry, and Other Stakeholders

In addition to the collaboration at the federal level, FDA also is working closely with our other government and industry partners to enhance food defense. For example, earlier this year, FDA made available on our website the Food Related Emergency Exercise Boxed set (FREE-B). This is a compilation of five scenarios based on intentional and unintentional food contamination events, which was developed in collaboration with CDC and USDA. FREE-B is designed to assist government regulatory and public health agencies in assessing existing food emergency response plans, protocols, and procedures or plans that are being revised or developed. It provides stakeholders with a variety of options to test and improve their capabilities to respond to food-related human or animal health emergencies. It is predicated on strengthening existing collaborations and partnerships between and among neighboring jurisdictions, as well as with other stakeholders (private sector, law enforcement, medical community, and first responders).

On March 23, 2011, FDA launched the Food Defense Mitigation Strategies Database. This new resource is designed for companies that produce, process, store, package, distribute, and/or transport food or food ingredients. The database provides a range of preventive measures that companies may implement to better protect their facility, personnel, operations, and products.

In 2008, FDA made available an educational program called Employees FIRST (Follow, Inspect, Recognize, Secure, Tell). Food industry managers can include this material in their ongoing employee food defense training programs. Employees FIRST educates front-line food industry workers about the risk of intentional food contamination and the actions they can take to identify and reduce these risks. FIRST is available in seven languages.

In 2003, FDA issued guidance on the preventive measures the food industry may take to minimize the risk that food will be subject to tampering or other malicious, criminal, or terrorist actions. FDA issued a general guidance entitled “Food Producers, Processors, and Transporters: Food Security Preventive Measures.” The guidance is designed as an aid to firms that produce, process, store, repack, relabel, distribute, or transport food or food ingredients. In addition, we have issued specific security guidance for the milk industry, for importers and filers, for retail food stores and food service establishments, and for cosmetic processors and transporters. The guidance was updated in 2008 to include a self-assessment checklist. During domestic inspections and import examinations, FDA’s field personnel, as well as our state counterparts, continue to hand out and discuss these guidance documents.

In 2007, FDA (in cooperation with CDC, USDA, and state and local organizations representing food, public health, and agricultural interests) initiated the ALERT food defense awareness program. ALERT identifies five key points that industry and business can use to lower the risk of intentional food contamination along the entire farm-to-table supply chain:

- How do you **assure** supplies and ingredients are from safe and secure sources?
- How do you **look** after the security of the products and ingredients in your facility?
- What do you know about your **employees**?
- Could you provide **reports** about the security of your products, while under your control?
- What do you do and who do you notify if you have a **threat**?

We have prepared ALERT materials in several languages and offer training on the ALERT system on our website that is suitable for state, local, and industry stakeholders.

Laboratory Enhancements

An additional step in enhancing our response capability is to improve our laboratory capacity.

An important component of controlling threats from deliberate foodborne contamination is the ability to rapidly test large numbers of food samples that could potentially be contaminated for a broad array of biological, chemical, and radiological agents. To increase surge capacity, FDA has worked in close collaboration with USDA's Food Safety Inspection Service to establish the Food Emergency Response Network (FERN) to include the majority of the nation's government

laboratories capable of analyzing foods for agents of concern. FERN is continuing to expand its capacity and capabilities through agreements with other federal, state, and local government laboratories. At present, the network includes 172 laboratories representing all 50 states and Puerto Rico. Participation in FERN continues to grow. FERN comprises a nationwide network of federal, state, and local government food laboratories working together to build the capacity to test the safety of thousands of food samples, thereby enhancing the ability to swiftly respond to a terrorist attack on the nation's food supply.

The FERN network has already proved to be a critical asset. It has been invaluable in providing surge capacity to handle the analysis of food samples during large-scale foodborne illness outbreaks. FERN and FDA field laboratories have also been instrumental in the rapid development of new testing methodologies required to meet the ever-changing threats to the nation's food supply. For example, early in the *Escherichia coli* O157:H7 outbreak associated with fresh spinach a few years ago, FERN and FDA analysts, working with CDC's Laboratory Response Network, approved a more rapid FERN method that substantially improved testing of spinach samples, as it allowed for the rapid detection of the pathogen at lower levels than previously possible. In response to the Deepwater Horizon oil spill in the Gulf, FDA and FERN chemistry laboratories were able to develop and implement a much more rapid analytical method for the detection of oil residues in the tissue of Gulf seafood. This new method allowed the Gulf fishing waters to be safely reopened much quicker than anticipated and continues to be used for sample analysis to ensure the safety of the seafood from that area.

To respond to high priority chemical and microbial animal feed and animal drug contamination events, FDA also recently initiated the Veterinary Laboratory Response Network (Vet-LRN) to enhance collaboration between federal and state agencies and veterinary diagnostic laboratories. This network is intended to provide additional laboratory capacity and expertise to help respond to such events. In addition, as contamination of animal feed or animal drugs could signal potential contamination in human food, this network will also contribute to efforts to protect the human food supply.

Now, I would like to mention a few of the provisions in FSMA that will provide further protections for American consumers.

FDA Food Safety Modernization Act

On January 4, 2011, President Obama signed into law FSMA. This landmark legislation gives FDA a modern mandate and toolkit to improve the safety of the country's food supply. It will provide further protections for American consumers from both intentional and unintentional contamination.

FSMA shifts our food-safety focus from reaction and response to prevention, so that prudent preventive measures will be systematically built into all parts of the food system. For the first time, FDA has a legislative mandate to require comprehensive, science-based preventive controls across the food supply. The law clarifies that people and businesses that provide food to the

public are responsible for taking the steps necessary to ensure that they've identified and controlled the hazards that could make food unsafe.

FSMA also provides significant new authorities to help ensure that food from abroad is as safe as food produced domestically. For example, it requires importers to perform verification activities to ensure imported food is safe. Although FDA will continue to carry out other measures to enhance the safety of imported food and to conduct risk-based electronic screening of all imported food shipments, this new requirement for importers to verify safety will provide an extra assurance that imported food is safe.

Specifically to address the threat of intentional contamination, among other provisions, FSMA directs FDA, in consultation with DHS and USDA, to issue regulations to require appropriate science-based mitigation strategies or measures to protect certain high-risk foods against intentional contamination. Prior to enactment of FSMA, FDA could recommend, but not require, implementation of such food defense measures.

CONCLUSION

In conclusion, due to the enhancements being made by FDA and other agencies and due to the close coordination between the federal and state food safety, public health, law enforcement, and intelligence-gathering agencies, the United States food defense system is stronger than ever before. Although we have made progress, we are continuously working to improve our ability to prevent, detect, and respond to terrorist threats and other acts of intentional contamination.

Thank you for this opportunity to discuss our food defense activities. I would be pleased to respond to any questions.

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